

# '08: FORECAST

ONCOLOGY INDUSTRY EXPERTS PROVIDE PERSPECTIVE ON THE COMING YEAR — INTERVIEWS CONDUCTED BY DON SHARPE

## »» The Community Cancer Center Perspective:

Interview with Christian Downs, JD, MHA, Executive Director, Association of Community Cancer Centers



Christian Downs, JD, MHA

**OBR:** *When MMA first hit, it was thought that there would be a movement in treating cancer patients from the community practice to the hospital outpatient setting. Has that happened? How do you think '08 will compare with '07 in movement from the practice setting to the hospital outpatient setting?*

**CD:** We haven't really seen a wholesale movement from the physician office setting to the hospital outpatient setting as was predicted. There are a couple of reasons for this. First, there are very few fluid markets where the cancer center is geographically close to the oncologist's office making the move easy and manageable. The second reason is that the financial impact of MMA on the physician office turned out to be less than originally expected. In other words, the ability of the physician office to absorb the reduction in revenue from infusions turned out to be greater than expected. This is probably because offices were able to tighten their belts and shift some of the burden to private insurance. This is not ideal or necessarily business-like, but is what happened.

It is doubtful that there will be a significant economic change in '08 that would change this pattern of treatment. There is one lingering concern though. The reduction in revenue from ESAs in '08 could change the financial picture in the practice setting and force a patient flow shift, but that probably wouldn't happen until late in the year if at all.

**OBR:** *The big story in this setting is the change in the Medicare HOPPS payment for '08. Please explain.*

**CD:** It is important to understand that unlike the physician office setting where the payment rate for drugs is set by statute, in the hospital outpatient department CMS has more leeway in setting the payment. Around the time of MMA, CMS set the payment rate for drugs in the HOPPS equivalent to the payment in the physician office setting. The main reason they did this is because they said they did not have good data indicating what the reimbursement rate should actually be set.

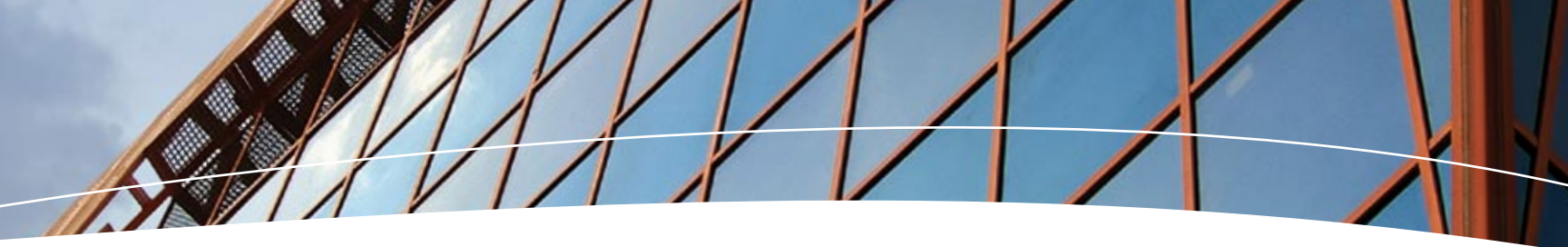
Unfortunately, in '07 CMS looked at previous years' claims data and determined that they could reimburse at a rate of ASP +3%. This would be a dramatic change so they decided to ease into it and "split the difference" and arrived at a reimbursement rate of ASP +4.5% rounded up to ASP +5%. So in '08 the reimbursement rate in the hospital outpatient setting will be ASP +5%, but CMS plans to go to ASP +3% in '09.

**OBR:** *That sounds difficult in '08 and very ominous for '09. How does ACCC plan to help out in '08?*

**CD:** Well, the claims data that CMS used is notoriously inaccurate and is a poor proxy for actual costs. ACCC plans to work hard to educate CMS and Congress that ASP +3% does not accurately reflect the cost of providing cancer care to Medicare beneficiaries. If there is good news it is that I don't think we'll see private insurers go to ASP +3% in the hospital setting. Hospitals seem to have some more leverage on the private side.

**OBR:** *How are hospital cancer centers evolving in response to the change in reimbursement in '08?*

**CD:** There has been a significant capital investment in cancer centers in things like surgery and imaging that allows them to absorb some of the loss in drug revenues. The change to ASP +5% will hurt them, but not shut them down.



## »» The Investment Bank Perspective:

Interview with Jason Kantor, PhD, Managing Director, RBC Capital Markets

The long-term concern is that at ASP +3% the hospital CEO may not want to be in the cancer treatment business anymore. We don't know where the breaking point is, but we know we're getting dangerously close to it at ASP +3%. In this scenario the oncologists' offices will have to see every kind of patient, including Medicaid and uninsured patients, and the loss of co-pay revenue will be financially devastating to the practice.

**OBR:** '08 seems to be a pivotal year as the hospital outpatient setting braces for a dramatic reimbursement change in '09. What are your long-term concerns, and what is the long-term good news?

**CD:** The principal long-term concern is that inaccurate reimbursement, things like ASP +3%, reductions in reimbursement for imaging procedures, not adequately paying for radiopharmaceuticals, will prevent cancer centers from staying on the cutting edge of treatment. This would negatively affect the bottom line which is patient care.

On the other hand, the good news is that most hospitals have made a commitment to cancer care. They have invested in their infrastructure, improved their financial and managerial processes, and brought community cancer care to a new level. ACCC is going to continue to work to make sure it stays there. **DS**

**OBR:** Let's start off looking in the rear-view mirror. What events in '07 raise concerns for you in '08?

**JK:** Probably the single largest external issue for the industry as a whole is the FDA and ODAC. The question is whether the standards are changing right now. If so, what are they changing to? We saw the FDA not follow the recommendation of their advisory committee for Provenge, and it will be very interesting to see what their decision is regarding the negative recommendation for Avastin in breast cancer. The regulatory environment has widespread implications overriding the whole industry.

**OBR:** Are there any particular environmental factors that concern you regarding the health of the industry as we start '08?

**JK:** In oncology, in particular, there is an ongoing debate about the cost of new therapies. I think that companies need to be rewarded for their innovation, but some have questioned the cost/benefit analysis and the societal impact of these drugs. I believe the cost/benefit issue will be debated throughout '08, especially because it is an election year and this could impact on the perception of the biotech industry.

Underlying the cost/benefit analysis is the ongoing political debate regarding approval of generic biologics. This particular concern is very hard to predict for '08. We feel as though we have strength in predicting outcomes of clinical trials because that prediction is scientific in nature, but we find ourselves less effective at predicting what Congress is going to do.

**OBR:** We saw only four new oncology products approved in '07 as compared with five in '06. Do you think we are in a downward trend for oncology with tougher standards for approval?

**JK:** On the one hand, you can't argue with numbers, but in reality there are too many variables to draw conclusions. There is certainly no slowing down of applications, clinical studies, and oncology drug development.

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## »» The Investment Bank Perspective (Cont.):

Interview with Jason Kantor, PhD, Managing Director, RBC Capital Markets

What I think we learned throughout '07 is that the best way to get a drug approved is to hit the primary endpoint. The FDA is scientifically driven and they want you to prove your hypothesis, and prove it well.

**OBR:** *What are your thoughts on the influence of CMS on prescribing habits if a new therapy finally makes it to market?*

**JK:** I don't have a strong view on CMS, but it is reasonable to assume that the government will try and reduce use of drugs. They tried to limit use of ESAs in the late '90s, but they didn't have scientific evidence of concerns with the therapy. This time they have the clinical studies to reinforce their decision, and thus influence prescribing habits. You could look for more such issues when the scientific evidence is there.

**OBR:** *What oncology products are you aware of that are maturing in '08 and may present data, go to an ODAC for review, or have a PDUFA date that may significantly change the share price of the company?*

**JK:** I can only comment on the companies/products that we're covering at RBC Capital Markets. A snapshot would include the Phase 3 data on MyVax from Genitope (data not yet released as of this printing). We're also watching for the additional Phase 3 data on Avastin in breast cancer, and the data on Rituxan outside of oncology in lupus and MS will be important in '08. We know that BMS and Medarex will be filing a BLA for their anti-CTLA-4 antibody in '08 and more Phase 3 data evaluating this product will be presented. And, I've really only scratched the surface; '08 looks like it will be a very busy year for oncology with no shortage of news.

**OBR:** *In your opinion, how does the oncology industry compare with other disease areas within industry?*

**JK:** Oncology could be characterized as having phenomenal scientific innovation leading to modest incremental patient benefit. In looking at some of the early clinical studies expected in '08, I am very excited for ASCO and ASH. I expect we'll see novel mechanisms of action, new developments with monoclonal antibodies, and unique applications of the discoveries researchers have made in understanding the biology of cancer. I hope that some of this technology demonstrates clinical proof of concept at the Phase 2 level this year. **MS**

## » The Community Oncologist's Perspective:

### Interview with Thomas Marsland, MD, Florida Oncology Associates



Thomas Marsland, MD

**OBR:** *Economically speaking, do you expect '08 to be a net worse/same/better year for your practice than it was in '07?*

**TM:** I have to answer that in reference to the particular operating and business conditions unique to our practice. At Florida Oncology Associates we expect '08 to be somewhat worse in the infusion business, but not

drastically so because we expect ASP to be stable or go up slightly. Impacting on our infusion business will be erosion on the Sustainable Growth Rate and private payers following the Medicare model and transitioning to an ASP reimbursement model. We hope to make up for losses in the infusion business with growth in our imaging services and a merger with a local urology group, although this merger will decrease our per study fee.

**OBR:** *What business segment of your practice i.e. infusion services, pharmacy (orals), radiation services, imaging, lab services, or research is likely to be the most positive for your practice in '08?*

**TM:** We are adding a third PET/CT scanner which will allow us to see the largest increase in revenue coming from imaging. As I mentioned earlier we are merging with a urology group and when that is complete we will expand into the MRI business beginning with urologic tumors and then developing breast programs. We expect to see some growth in laboratory services, especially from new indications for circulating tumor cells (colon) and we plan to ramp up utilization of our dispensing pharmacy.

**OBR:** *Can you tell us which of these business segments will undergo the greatest scrutiny in your practice in '08 and which*

*is likely to be the least economical business segment? What do you plan to do to improve the efficiencies of this segment?*

**TM:** The business segment that will get the biggest scrutiny at FOA will be the traditional infusion/chemo business. Unfortunately, we are not very efficient, probably because we have been fat and happy for too long, and now we need to take this segment seriously. Our plan to improve efficiencies includes good scheduling of infusions and office visits, making the most of our staff's time, and combining our two St Augustine offices. By doing this, we are projecting that we can save close to \$200,000.

**OBR:** *What key business learnings would you urge to your fellow community practice oncologists to watch closest in '08 to improve their practice efficiency?*

**TM:** That depends on what sort of practice they are in. If they are in a relatively small drug infusion type practice (3, 4, 5, docs), they have very limited options. I'd say, be as efficient as you can, use staff wisely, and capture all your charges. My personal belief is that in the short-term, imaging offers the greatest returns in the 5-10 year timeframe. Other areas to consider as possible sources of revenue include specialty lab services that use genomics and proteomics, research, hospice, rehabilitation, and data sales.

**OBR:** *Looking forward, what are your greatest congressional or CMS concerns in '08?*

**TM:** Congress and CMS are always a concern to us. In general terms, the concern is that they will restrict the price of drugs and other services to an even greater extent. An even bigger threat is the expansion of prototype idea of the ESA restrictions regarding use. I'm greatly concerned that regulatory and legislative groups will try and restrict use of agents that will have a negative impact on the financial viability of the private practices. **DS**

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## » The Capitol Hill Perspective:

Interview with Marc Samuels of HillCo Partners, a Washington-DC based healthcare strategic business advisory firm

**OBR:** *What are the hot topics in Washington right now that could have a large impact on oncologists in '08?*

**MS:** The most visible topic for oncologists is the scheduled drop in physician fees. A Medicare bill was passed December 19th and as of this interview awaits the President's decision. As a result, physicians will gain a modest one half of one percent increase and not suffer the ten percent decrease in rates scheduled for January 1, 2008. The measure is only good for six months, however, and so lawmakers will have to come back and address the issue in January. The bill also implements an HHS OIG recommendation to require CMS to adjust its Average Sales Price (ASP) calculation to use volume-weighted ASPs based on actual sales volume. It is unclear how that will affect oncology at this time but anything materially impactful could be addressed in January. On the other hand, the move to add "Comparative Effectiveness" reform in some manner into the Medicare (and Medicaid) programs may dictate their practice patterns and with restricted choices will come less opportunity to find financial advantage.

It is also interesting to note that the National Comprehensive Cancer Network (NCCN) is working to get its compendia accepted as one of the Medicare approved compendia through the Medicare package; and or affect the language regarding compendia selection in Medicare Part D. Since its creation the Medicare Part D program has had language from the Medicaid statute. Unlike in Medicare Part B the current language does not allow the Secretary discretion when selecting approved compendia. NCCN and advocates hope to change this quirk in the law. They are making some headway as I just saw the agency acknowledge it was looking at ways to potentially administratively change the Part D compendia to mirror activity on the Medicare Part B side.

**OBR:** *It took you until the end of the first question, but you mentioned "Comparative Effectiveness" as does everyone in*

*Washington. Please tell us where we stand with Comparative Effectiveness initiatives across the government.*

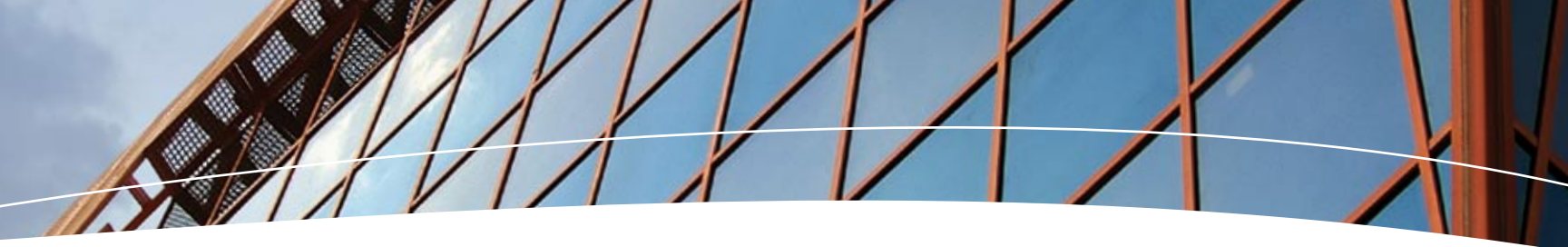
**MS:** Comparative Effectiveness continues to be rumored to be part of the new Medicare bill. The concern for oncologists is that if it is approved oncologists may be told they can only use one drug or one procedure which reduces the independence of the oncologist and inserts bureaucrats and policy makers in the medical decision-making process. Proposals are many, and come from groups as diverse as MedPac to the HMO lobby to the Blue Cross Blue Shield Association. The debate hinges on whether to designate an existing agency, say the Agency for Healthcare Research and Quality (AHRQ) or to create a new agency and pull powers and duties away from CMS, FDA, AHRQ and other agencies. I think this movement is the one time, in recent times, where the private market is ushering in a new wave of evidence-based medicine ideas, a focus on better quality and value for the healthcare dollar, through introduction of Healthcare IT and EMR and care management (in companies like McKesson). My money is on AHRQ as Carolyn Clancy, its current director, is a trustworthy figure in the minds of government, business and the think tanks/advocates.

**OBR:** *We heard a lot about follow-on biologics and proposed legislation to approve generic versions of biologics in '07. Where do you think we stand in '08?*

**MS:** The debate to define an approval pathway will continue in '08, and ultimately, I expect congress to get very close if not approve something in '08.

**OBR:** *Do you expect Congress to take steps to intervene in the relationship between oncologists/physicians and industry in '08?*

**MS:** No. There will be more action at the state level restricting the promotional activities of pharmaceutical companies. I think an interesting example of this move-



ment is where in some states sales representatives are being asked to register as lobbyists if they are in contact with Medicaid.

New proposed marketing laws which impact physicians in clinical trials and companies who impart data and clinical information on these physicians are becoming more prevalent. State legislatures are not passing the laws, however, choosing to allow the physicians to adhere to the AMA Code of Ethics and for pharmaceutical and biotechnology companies to adhere to ethical standards set out under their own associations and the dictates of the federal and state inspectors general.

**OBR:** *And what do you think industry should be most concerned about in '08?*

**MS:** The biggest threat to industry in '08 is Comparative Effectiveness. It has the effect today of regulating markets before they form because of its relative newness to how we've done business with Medicare and Medicaid in the past. Many companies have global reach and so are used to NICE and the European and Japanese regulatory structures, but ours in the United States has always been different. It may cut differently for high-cost oncologics, anti-emetics or genomics/diagnostics than in the past; but if industry works in a collaborative fashion with regulators it could also provide opportunity. What we are proposing is transparent; AHRQ has released transparent guidelines for the way it will conduct evidence-based reviews. It is my understanding that NICE is not transparent. Some potential uses for Comparative Effectiveness include:

- (1) Creating a tiered payment structure that pays providers more for those services that show more value to the program;
- (2) Creating a tiered cost-sharing structure that requires lower cost sharing for those services that show more value to the program;

- (3) Not paying the additional cost of a more expensive service if evidence shows that it is clinically comparable to its alternatives; and
- (4) Requiring manufacturers to enter into a risk-sharing agreement, which links actual beneficiary outcomes to the payment of a service based on its comparative effectiveness.

Another area industry should be concerned about is the fact that there is no announced successor to USP as a Medicare-approved compendium. This is inhibiting the ability of physicians and medical centers to submit for coverage of broader uses of anti-cancer and supportive therapies. As mentioned earlier, the new Medicare bill may address this concern, but right now I think there is hesitation to use drugs for non-compensia listed indications or those listed in DrugPoints or NCCN which are not yet Medicare-approved. There is a new revitalized tone in oncology at the American Hospital Formulary Services through a partnership with the Foundation for Evidence-Based Medicine that many of us hope will be a positive force for change across oncology.

The movement to ASP +5% in the hospital outpatient setting is also likely to impact on industry. Perhaps more threatening for industry is the indication from CMS that they could go as low as ASP +3%. It is a wakeup call to hospitals that data collection efforts must improve if they want to showcase to CMS or other payers that they are being insufficiently reimbursed for procedures, products, and services.

And, as I mentioned earlier the impact on the imaging industry could be substantial depending on where the \$6 billion is taken from for the physician patch.

The good news for industry is that the importation debate seems to have lessened and right now I don't expect that to be a big issue in '08. **DS**